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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09 939,209 | 08 24 2001 | Pat Ressler Levitt | 00-539-US | 3394 |

7590 02.07.2003

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EXAMINER

QIAN, CELINE X

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1636

DATE MAILED: 02.07.2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,209

Applicant(s)

LEVITT ET AL

Examiner

Celine X Qian

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other

DETAILED ACTION

Claims 1-45 are pending in the application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20 and 40-43, drawn to an isolated nucleic acid, a hybridization probe to the nucleic acid, a vector comprising said nucleic acid, and a host cell comprising said vector, classified in class 536, subclass 23.1, 24.31, class 435, subclass 320.1, 325.
- II. Claims 21-26, drawn to a method for diagnosing/determining susceptibility of schizophrenia by detecting a variation in the RGS4 gene, classified in class 435, subclass 440.
- III. Claims 27 and 28, drawn to a method for diagnosing/determining susceptibility of schizophrenia by determining whether there is reduced expression of RGS4 mRNA, classified in class 536, subclass 24.5.
- IV. Claims 29, 30, 31 and 32, drawn to a method for diagnosing/determining susceptibility of schizophrenia by determining whether there is reduced expression of RGS4 protein, classified in class 530, subclass 350.
- V. Claims 33-35, drawn to a method for treating schizophrenia by altering RGS4 protein levels, classified in class 530, subclass 351.
- VI. Claims 36 and 37, drawn to a kit for diagnosing schizophrenia in a patient comprising antibodies to RGS4 and a detector, classified in class 424, subclass 130.1.

VII. Claims 38 and 39, drawn to a kit for diagnosing schizophrenia comprising a detector of RGS4 transcript levels and a standard to ascertain altered levels of said transcript, classified in class 536, subclass 24.3.

VIII. Claims 44 and 45, drawn to a transgenic mouse comprising a RGS4 disruption in its genome, classified in class 800, subclass 18.

The inventions are distinct, each from the other for following reasons.

The inventions of Groups I, VI-VIII are patentably distinct from each other because the inventions are drawn to materially distinct compositions that are not directly related. The nucleic acid, the kit comprising antibodies, the kit comprising RGS4 detector and the transgenic mouse comprising a RGS4 disruption are chemically, biologically and functionally distinct from each other. Therefore, the invention of Groups I, VI-VIII are patentably distinct.

The inventions of Groups II-V are patentably distinct from each other because the inventions are drawn to methods that require different starting materials and modes of operation. Each method requires distinct steps. Therefore, the inventions of Groups II-V are patentably distinct.

The inventions of Groups I, VI-VIII and II-V are patentably distinct from each other because the inventions are drawn to compositions and methods that are not directly related. The products of Groups I, VI-VIII can be used in methods that require different technical considerations and materially different reagents from the method of Groups II-V. The method of Group II-V can be practiced with products that have different chemical structures than the products of Groups I, VI-VIII. Therefore, the inventions of Groups I, VI-VIII and II-V are patentably distinct.

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Groups I and II are comprised of multiple inventions which are the products or methods drawn to different and distinct sequences which do not render obvious each other and thus are patentably distinct. If any of Groups I and II are elected, applicants must elect a single invention which is the product or method drawn to one specific sequence, and one mutation variation to which the claims will be restricted. Note, this restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase of size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for reviewing the computer search results. Therefore, the limited resources of the Office no longer permit examination of more than one sequence in an application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. A search of the subject matter of one invention would not be co-extensive with a search of the other invention, and therefore the search would be burdensome. Each invention is capable of supporting a separate patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
February 2, 2003

Anne-Marie Falk

ANNE-MARIE FALK, PH.D.
PRIMARY EXAMINER